K061648 1 of 2

510(k) SUMMARY

SEP 1 1 2006

NAME OF FIRM:	DePuy Orthopaedics Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration No.: 1818910
510(k) CONTACT:	Nancy Friddle Team Leader, Regulatory Affairs Tel: (574) 371-4923 Email: nfriddle@dpyus.jnj.com
TRADE NAME:	Depuy Graduated Compartmental Knee (GCK)
COMMON NAME:	Compartmental Knee Prosthesis System
CLASSIFICATION:	Knee joint femorotibial, metal/polymer semi-constrained cement prosthesis (per 21 CFR 888.3530), Class II Device
DEVICE PRODUCT CODE:	NPJ, HRY, KRR
SUBSTANTIALLY EQUIVALENT DEVICES:	Stryker Compartmental Knee System (K052917) Preservation® Unicondylar Knee System (K010810) PFC Sigma® Knee System (K943462) DePuy Sigma XLK Tibial Inserts (K040166)

DEVICE DESCRIPTION:
The DePuy GCK is composed of unicompartmental femoral components, patellofemoral trochlear components, unicompartmental tibial components and patellar components. These components may be used in various combinations to create a single or multi-compartmental knee replacement prosthesis.

The GCK Unicompartmental Femoral Components are a modification of the Preservation® Unicondylar Femoral Components. They are manufactured from Co-Cr-Mo and are available in sizes 1-6 in left medial / right lateral and right medial / left lateral versions. The fixation surface is available with or without a beaded porous coating.

The GCK Patellofemoral Trochlear Components are a modification of the PFC Sigma® Femoral Components. They are manufactured from Co-Cr-Mo and are available in sizes 1-5 in left and right versions. The fixation surface is available with or without a beaded porous coating.

The GCK All Polyethylene Unicompartmental Tibial Components are a modification of the Preservation All Polyethylene Unicondylar Tibial Components. They are manufactured from XLK cross-linked polyethylene and are available in sizes 1-6, 5 thicknesses (8-12mm) and in left medial / right lateral and right medial / left lateral versions.

The patella components used with the GCK are the PFC Sigma Inset, Oval and Round Dome Patellae. These patellar components have been previously cleared for use in total knee arthroplasty.

INDICATIONS FOR USE:
The DePuy Graduated Compartmental Knee (GCK) is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

The GCK is indicated for single or multi-compartmental knee replacement in skeletally mature individuals with osteoarthritis, posttraumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces or a history of gout or pseudogout. All GCK components are intended for CEMENTED USE ONLY.

SUBSTANTIAL EQUIVALENCE:
Based on similarities in indications, intended use, design, materials and method of manufacture, DePuy believes that the GCK is substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2006

DePuy Orthopaedics, Inc
% Ms. Nancy Friddle
Team Leader, Regulatory Affairs
P.O. Box 988
Warsaw, Indiana 46581

Re: K061648
Trade/Device Name: DePuy Graduated Compartmental Knee
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: NPJ, HRY, KRR
Dated: June 12, 2006
Received: June 13, 2006

Dear Ms. Friddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchmp
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K061648

Device Name: DePuy Graduated Compartmental Knee

Indications for Use:

The DePuy Graduated Compartmental Knee (GCK) is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

The GCK is indicated for single or multi-compartmental knee replacement in skeletally mature individuals with osteoarthritis, posttraumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces or a history of gout or pseudogout. All GCK components are intended for CEMENTED USE ONLY.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061648